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PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, JOSEPH MACKEN, COMMISSIONER LINDA A. WATTERS, AFSCME DISTRICT COUNCIL 47 HEALTH &WELFARE FUND, VICTORIA SCOFIELD, JANET MCGRORTY, RICHARD TIKKURI, WISCONSIN CITIZEN ACTION, UNITED SENIOR ACTION OF INDIANA, NORTH CAROLINA FAIR SHARE,

Petitioners,

v.

ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, L.P.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF

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CORPORATE DISCLOSURE STATEMENT

Petitioner's corporate disclosure statement was set forth at page *ii* of its Petition for a Writ of Certiorari, and there are no amendments to that statement.

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ARGUMENT

In their *Brief in Opposition* ("Oppo."), Respondents incorrectly assert that this case presents case-specific issues that this Court should not review. To the contrary, this case presents the sweeping issue of whether 21 U.S.C. §§ 337 and 352(n) bar all state-law claims for deceptive advertising of prescription drugs, even if the claims are wholly consistent with the FDCA, with FDA regulations, with FDA findings, and with the approved label. Contrary to Respondents' argument, the majority based its preemption ruling on a broad interpretation of sections 337 and 352(n) that all such claims are preempted, and specifically rejected Respondents' argument that Petitioners' claims conflict with the Nexium label or with FDA regulations. The Third Circuit's ruling would apply to all claims for deceptive advertising of prescription drugs, eliminating the issue of whether a claim conflicts with or is consistent with the prescription drug's label. The ruling is in direct conflict with recent decisions of this Court and the highest courts of certain states. That ruling merits review by this Court.

I. THE THIRD CIRCUIT REJECTED RESPONDENTS' ARGUMENT THAT PETITIONERS' CLAIMS CONFLICT WITH THE FDA'S APPROVAL OF THE NEXIUM LABEL AND HELD THAT 21 U.S.C. §§ 337 AND 352(n) PREEMPT ALL STATE-LAW CLAIMS FOR DECEPTIVE ADVERTISING OF PRESCRIPTION DRUGS

The majority in the Third Circuit rejected Respondents' argument that Petitioners' claims conflict with the Nexium label, and instead held that all state-law claims for advertising prescription drugs are preempted by the FDCA and its enabling regulations. The majority first rejected Respondents' case-specific argument, stating:

> To the extent that the complaint alleges that Zeneca marketed Nexium as superior to Prilosec, those claims of superiority might be actionable inasmuch as such comparisons are not supported by the labeling and therefore might be false or misleading.

499 F.3d at 246.

The Court then plainly held that Petitioners' claims are preempted solely because all state-law claims for deceptive advertising of prescription drugs are preempted, regardless of whether there is a conflict

between the state-law claim and the FDCA, FDA regulations, FDA findings or the label at issue. The majority stated:

> Implied conflict preemption of state consumer fraud laws is required in this setting because both the FDCA and FDA regulations provide specific requirements for prescription drug advertising. Congress specifically determined that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The high level of specificity in federal law and regulations with respect to prescription drug advertising is irreconcilable with general state laws that purport to govern all types of advertising. *See, e.g.*, 21 U.S.C. § 352(n); 21 C.F.R. § 314.81(b)(3). Accordingly, the plaintiffs' state consumer fraud claims are preempted.

Id. at 251-52.

The majority reaffirmed that holding when it held that Petitioners' claims are preempted even if the FDA explicitly told Respondents that they were not permitted to market Nexium as superior to Prilosec:

> Additionally, although the plaintiffs suggest that some additional facts might be pled in order to cure the defects of the complaint, amendment would be futile. In particular, the plaintiffs state that they

> could allege that "in negotiations between the FDA and AstraZeneca regarding Nexium labeling, the FDA stated it would not approve any representations by AstraZeneca that Nexium is more effective than Prilosec, and AstraZeneca responded it would not make any such statement." This will not overcome the deficiencies in the complaint because the advertisements are not subject to state consumer fraud law, as explained in part III.

499 F.3d at 252-53.

In the concluding section of its opinion, the majority reiterated the sweeping nature of its decision:

> By specifically excluding advertisements covered by 21 U.S.C. § 352(n) and the regulations promulgated thereunder from the scope of 15 U.S.C. § 52, Congress signaled its intent to give the FDA exclusive authority to regulate prescription drug advertising. The FDA has established specific regulations regarding such advertising. To allow generalized state consumer fraud laws to dictate the parameters of false and misleading advertising in the prescription drug context would pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users. Accordingly, the state consumer fraud laws are preempted by the extensive federal legislative and regulatory framework.

499 F.3d at 253. Finally, in dissent, Judge Cowen

explained that the majority held that "the FDCA and the implementing regulations displace the Delaware Consumer Fraud Act and the consumer protection statutes of the fifty states." 499 F.3d at 254.

Thus, contrary to Respondents' arguments, the Third Circuit rejected Respondents' case-specific assertion that Petitioners' claims conflict with the FDA's approval of the Nexium label, and instead held that the FDCA preempts ***all*** state-law claims for deceptive advertising of prescription drugs.

II. THIS COURT SHOULD REVIEW THE HOLDING THAT THE FDCA PREEMPTS ALL STATE-LAW CLAIMS FOR DECEPTIVE ADVERTISING OF PRESCRIPTION DRUGS

The Third Circuit's holding that 21 U.S.C. §§ 337 and 352(n) bar all state-law claims for deceptive advertising of prescription drugs conflicts with decisions by this Court, by state courts of last resort and by federal appellate courts, as explained in the Petition. Respondents' arguments to the contrary are unavailing, because they rest on the incorrect premise that the majority of the Third Circuit panel held that Petitioners' claims are preempted because of a conflict with Nexium's label.

For example, Respondents incorrectly assert that the meaning of Section 202 of the Drug Amendments of 1962 "is not at issue because respondents have always maintained that, under ordinary preemption principles, there is a conflict between petitioners' claims and federal law." Oppo. at 25. The issue is not what Respondents

may have ***maintained*** but rather what the Third Circuit held. And, as discussed in the Petition and above, the majority did not agree with Respondents' contention that "ordinary preemption principles" bar Petitioners' claims. *See* 499 F.3d at 246 ("To the extent that the complaint alleges that Zeneca marketed Nexium as superior to Prilosec, those claims of superiority might be actionable inasmuch as such comparisons are not supported by the labeling and therefore might be false or misleading."). Instead, the majority held that section 352(n) bars ***all*** state-law claims for deceptive advertising of prescription drugs, even though section 202 of the Drug Amendments of 1962, which created section 21 U.S.C. § 352(n), states that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." P.L. 87-781 § 202, 76 Stat. 793 (Oct. 10, 1962). Therefore, contrary to Respondents' argument, section 202 of the Drug Amendments Act of 1962 is plainly at issue in this matter.

For the same reasons, cases interpreting section 202 of the Drug Amendments Act of 1962 and 21 U.S.C. § 352(n) as requiring an actual conflict with state law in order for preemption to apply are plainly relevant. For example, in *Levine v. Wyeth*, 2006 Vt. 107 (2006), *review granted*, __ U.S. __, 169 L. Ed. 2d 845 (Jan. 18, 2008), the Court held that Section 202 means that "Congress intended that the FDCA would leave state law in place except where it created a 'direct and positive conflict' between state and federal law." *Id.* at ¶ 27. Similarly, in *Perez v. Wyeth Labs. Inc.*, 161 N.J. 1, 734 A.2d 1245

(1999), the Court held that under section 352(n), compliance with FDA regulations relating to the advertisement of prescription drugs creates a rebuttable presumption of legality but rejected the argument that section 352(n) preempts all state-law claims for deceptive advertising or prescription drugs.

In addition, the majority's reliance on 21 U.S.C. § 337 in holding that Petitioners' claims are preempted, *see* 499 F.3d at 251-52, conflicts with numerous decisions by this Court, as explained in the Petition. Most recently, this Court held in *Riegel v. Medtronic, Inc.*, __ U.S. __, 2008 U.S. Lexis 2013, at *5 (Feb. 20, 2008), that "the pre-emption clause enacted in the Medical Device Amendments of 1976, 21 U.S.C. § 360k, bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration (FDA)." This Court, however, explained that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at *30. In contrast, the Third Circuit majority held that sections 337 and 352(n) bar ***all*** state-law claims for deceptive advertising of prescription drugs, regardless of whether the claim parallels or instead conflicts with FDA regulations or findings.

The majority's reliance on section 337 also conflicts with a recent decision by the California Supreme Court. In *Farm Raised Salmon Cases*, __ Cal. 4th __, 2008 Cal. Lexis 1413, at *3 (Feb. 11, 2008), the Court held that section 337 does not preempt claims that "grocery stores violated state law by selling artificially colored farmed

salmon without disclosing to their customers the use of color additives." The Court explained that Section 337 does not apply to the state law claims presented here. "The statute, by its very terms, only implicates efforts to enforce *federal* law. What section 337 does *not* do is limit, prohibit, or affect private claims predicated on *state* laws." __ Cal. 4th at __, 2008 Cal. Lexis 1413, at *35 (emphasis in original). In contrast, the Third Circuit majority held that section 337 bars Petitioners' state-law claims in this matter, even though Petitioners do not seek to enforce federal law.

For all these reasons, and for the reasons stated in the Petition, the decision by the Third Circuit conflicts with decisions by this Court, by state courts of last resort and by federal appellate courts

III. THERE IS NO REASON FOR THIS COURT TO REVIEW THE THIRD CIRCUIT'S DECISION THAT PETITIONERS' CLAIMS ARE CONSISTENT WITH THE FDA'S APPROVAL OF THE NEXIUM LABEL OR TO ADDRESS ANY OF THE OTHER CASE-SPECIFIC ARGUMENTS RAISED BY RESPONDENTS

Respondents erroneously argue that regardless of the Third Circuit's sweeping holding, the Petition should be denied because the Third Circuit should have adopted a number of case-specific arguments proffered by Respondents. There is no reason for this Court to address Respondents' case-specific arguments and to decide whether the Third Circuit erred by not adopting those arguments. If this Court were to reverse the Third Circuit's sweeping decision that sections 337 and 352(n)

preempt all state-law claims for deceptive advertising of prescription drugs, the lower courts could then decide whether to address Respondents' case-specific arguments. The only issue that merits this Court's attention is the broad preemption holding, which has implications far beyond the confines of the particular dispute between Petitioners and Respondents.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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